IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

OAK HILL HOMETOWN PHARMACY Inc.,

Petitioner,

CASE NO. 2: 19-716

v.

UTTAM DHILLON, in his official capacity as Acting Administrator; and UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

MEMORANDUM IN SUPPORT OF PETITION FOR INJUNCTION TO DISSOLVE IMMEDIATE SUSPENSION ORDER

On August 8, 2019, agents with the United States Drug Enforcement Administration ("DEA") raided Oak Hill Hometown Pharmacy ("OHHP"), a community pharmacy in Oak Hill, West Virginia. With firearms brandished, those agents served on OHHP an *ex parte* Order to Show Cause and Immediate Suspension of Registration ("Ex Parte Suspension Order") issued by Acting Administrator Uttam Dhillon ("Administrator") on August 6, 2019. That Ex Parte Suspension Order caused two different and separate results. First, it put OHHP on notice that the DEA was seeking to revoke its Certificate of Registration ("Registration") which would be the subject of forthcoming administrative procedures. Second, the Ex Parte Suspension Order immediately suspended that Registration pending the eventual determination regarding revocation. In essence, there are two results, revocation, for which a party is entitled to a hearing an opportunity to respond before being deprived of a certificate of registration, and immediate suspension, for

which a party is not entitled to such protections. OHHP only challenges the second of those two results.

The Ex Parte Suspension Order based each of those results upon one of two preliminary findings reached by the Administrator. The first preliminary finding went to the revocation and provided that OHHP had filled Subutex prescriptions inconsistent with the public interest, requiring OHHP's response to the DEA's allegations to explain why its Registration should not be revoked under 21 U.S.C. §§ 823(f), 824(a)(4)&(c) ("Show Cause Finding"). The second went to the immediate suspension and asserted that OHHP's Registration was immediately suspended because its continued registration "constitute[s] 'an imminent danger to the public health or safety,'" pursuant to § 824(d) ("Preliminary Immediate Suspension Finding"). *See* Exhibit 2, *Ex Parte Suspension Order*, at 12. According to the Ex Parte Suspension Order, the Preliminary Immediate Suspension Finding was based on "the substantial likelihood that OHHP will continue to unlawfully prescribe controlled substances, thereby allowing the diversion of controlled substances, unless OHHP's [Registration] is suspended." *See id.* Due to that Preliminary Immediate Suspension Finding, agents confiscated OHHP's Registration and seized all of OHHP's scheduled medications, thus instantly depriving OHHP of the valuable ability to fill its patient's scheduled medications.[1]

[1] The Ex Parte Suspension Order does not constitute a final agency action for purposes of the Administrative Procedures Act ("APA"), 5 U.S.C. § 701 *et seq.* A final order is only reached in a DEA enforcement proceeding after the Administrator has received the Administrative Law Judge's ("ALJ") recommended findings of fact, recommended conclusions of law, and recommended decision. *See* 21 C.F.R. § 1316.67 (providing that the Administrator must issue a final order setting forth final rule, the findings of fact, and conclusions of law); *see also id.* at §1316.65 (explaining that the ALJ shall prepare recommended findings of fact and conclusions of law and a recommended decision for the Administrator after the hearing is held and the parties have submitted their proposals). Because the Ex Parte Suspension Order is not a final agency action, the APA, and its associated standard of review, does not apply. *See* 5 U.S.C. § 704 (making only (Continued)

OHHP seeks only the dissolution of the immediate suspension of its Registration by this Court.[2] In order to dissolve that immediate suspension, this Court need only reach a determination regarding the sufficiency of the Administrator's Preliminary Immediate Suspension Finding. Moreover, this Court — not an ALJ — is the forum to review that finding and the accompanying immediate suspension of a certification registration. *See Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 823-24 (5th Cir. 1976) (explaining that "plain language" of §824(d) "means that one faced with becoming the victim of the harsh expedient of suspension without prior notice may resort to the appropriate district court in search of appropriate relief"). Because the Ex Parte Suspension Order, and its Preliminary Immediate Suspension Finding, failed to satisfy the

final agency actions reviewable under APA); *see also U.S. Army Corps of Engineers v. Hawkes Co., Inc.*, 136 S. Ct. 1807, 1813 (2016) (explaining that final agency action reviewable by judiciary requires "the consummation of the agency's decisionmaking process — it must not be of a merely tentative or interlocutory nature" (citation and internal quotation marks omitted)). Moreover, as provided in the specific statutory provisions applicable to DEA administrative proceedings, only "final" determinations are reviewable by a federal court of appeals. *See* 21 U.S.C. § 877. This Court, as a district court of competent jurisdiction, is the proper forum to review the Administrator's immediate suspension of OHHP's Registration. *See Novelty Distrib., Inc. v. Leonhart*, 562 F.Supp.2d 20, 28 (D.D.C. 2008) (concluding that district court had jurisdiction to hear challenge to DEA's action under § 824(d) because such action was not final agency action).

[2] To be clear, OHHP does not challenge the Show Cause Finding or the potential revocation of its Registration. That finding, and any potential revocation, is the subject of administrative proceedings currently before a DEA ALJ. Although the ALJ is the proper adjudicatory forum for litigating the Show Cause Finding and the DEA's alleged basis for revocation, § 824(d) authorizes review and dissolution of an immediate suspension "by a court of competent jurisdiction." *See* 21 U.S.C. § 824(d). Therefore, OHHP's petition for this Court to dissolve the immediate suspension, and request for immediate reinstatement of its Registration, pending the administrative hearing regarding potential revocation, is statutorily permitted. Indeed, DEA ALJs have recognized that they do not possess the statutory authority to review an immediate suspension of a certificate of registration. *See Barry M. Schultz, M.D.*; Decision and Order, 76 Fed. Reg. 78,695, 78,697 (Dec. 19, 2011) ("[T]o the extent that the Respondent believes that the agency's immediate suspension of [his] registration was inappropriate, either substantively or procedurally, that matter is not reviewable by this tribunal, and must be pursued in the federal District Court.") (citing 21 U.S.C. § 824(d)).

statutory standard for immediate suspension in 21 U.S.C. § 824(d), this Court should dissolve the immediate suspension and restore OHHA's Registration forthwith.

I. FACTUAL BACKGROUND

A. OHHP begins serving its community and helps fight opioid use disorder by filling medications to treat that disorder.

OHHP has been a staple of the Oak Hill community since its inception in 2012. As a locally owned, family business, OHHP serves patients from Oak Hill and its surrounding areas. In short, OHHP was the fulfilment of a longtime goal of its part owner and head pharmacist, Martin Njoku, who has lived and worked as a pharmacist in that area for nearly thirty years. And shortly after its inception, OHHP's patient base soon began to grow. In 2016, historic and catastrophic floods left much of Greenbrier and Nicholas Counties underwater and its businesses closed. As a result, patients from those and other affected counties began filling their prescriptions at OHHP.

Like many businesses in West Virginia, especially those in the southern part of the State, the opioid epidemic also began to affect OHHP's business. In response to the epidemic, and in an effort to help remedy the deep scars that it has left on the community, OHHP filled prescriptions for a common medication, called Subutex, which was specifically approved by the FDA to treat patients with opioid use disorder. Subutex prevents withdrawals for those dependent on opioids and allows them to begin to reenter the workforce. Subutex is the brand name for a medication that contains only one active ingredient, buprenorphine. Buprenorphine attaches to opioid receptors, thus preventing the feeling of withdrawal. But unlike opiate street drugs, buprenorphine does not produce the same euphoric feeling or "high." *See* Exhibit 3, *Declaration of Martin Njoku*, at ¶ 3. Thus, it is well positioned to simultaneously prevent opioid dependent patients from experience excruciating withdrawal and permit those patients to live more productive and healthy lives.

But because of the stigma associated with treating patients suffering from addiction, many pharmacies declined to stock Subutex. Although Subutex is FDA-approved for use in what is referred to as Medication Assisted Treatment ("MAT") of opioid use disorder, many pharmacies refused to fill Subutex prescriptions. That refusal was primarily due to the stigma associated with Subutex and the patients who take it. In lieu of Subutex, some, but not all, of those pharmacies would fill another prescription written by physicians as part of MAT — Suboxone.

Suboxone is the brand name of a medication that combines buprenorphine and naloxone. With the addition of naloxone, which is an opioid antagonist, Suboxone is intended to be formulated to decrease the ability of patients to potentially misuse the buprenorphine. Suboxone's efficacy in that respect, however, has not been clearly demonstrated and is a point of medical discussion. In addition to both Subutex and Suboxone being FDA-approved for MAT, Subutex was often cheaper for patients than Suboxone — due partially to the fact that it had a generic version and Suboxone did not until late 2018. *See* Exhibit 3, at ¶ 4.

B. DEA serves an administrative warrant in November 2018 and interrogates OHHP employees on its practices related to filling Subutex, after which OHHP substantially reduced filling of Subutex prescriptions.

On November 28, 2018, DEA agents served an administrative warrant on OHHP. As part of that warrant, agents interviewed employees of the pharmacy and inspected its records. But the warrant, as well as the agents' investigation focused solely on OHHP's filling of Subutex prescriptions, nothing else. During their interviews and inspections, agents claimed that so-called "red flags of diversion" were present in OHHP's filling of Subutex. In DEA parlance, such "red flags" should cause a physician or a pharmacy to inquire further into the legitimacy of a prescription. But as OHHP employees explained to the DEA agents during their interviews, none

of the supposed "red flags" identified by those agents were actually red flags of diversion. And to the extent that they were red flags, OHHP was diligently detecting and resolving them.

The DEA agents expressed three primary concerns: (1) distance travelled by the patients, (2) the selection of Subutex rather than Suboxone; and (3) private pay for partial fills of prescriptions. With regard to the first, distance, the DEA agents expressed concern that patients from West Virginia were travelling to Pennsylvania to seek MAT and that patients were traveling anywhere from fifteen to fifty miles from their homes to OHHP in order to fill their prescriptions. Those concerns were premised upon the implication that patients would only travel such distances if something illicit was afoot, and therefore the travel was a red flag. Regarding the second category, agents worried that Subutex itself — despite being an FDA-approved medication to treat opioid use disorder — was a red flag that patients were diverting that medication for illicit purposes. Finally, DEA agents noted that many patients purchased only part of their prescription at any one time and did so without insurance covering any of that cost.

But the OHHP staff explained to DEA agents that they misunderstood the situation on the ground in rural West Virginia; neither the distance, the medication, nor the private payment for partial fills was a red flag. Instead, those characteristics were created by legitimate but unfortunate circumstances surrounding the treatment of opioid-dependent patients. In short, they were not indications of illicit diversion at all.

The OHHP staff explained that there were multiple reasons for the distance travelled by MAT patients. The staff described how there were simply not enough MAT providers in West Virginia. In order to administer MAT, a provider must obtain special DEA permission to prescribe medications for opioid use disorder. *See* 21 U.S.C. § 823(g). There were many counties in the State — including those near Oak Hill — where there *was not a single* MAT provider in the entire

county. *See* Exhibit 4, *Letter from West Virginia Board of Pharmacy*, at 2. But even in the areas where there were MAT providers, many were not accepting new patients and wait times could be years. Indeed, the number of MAT patients a provider can see is limited by Congress. *See* 21 U.S.C. § 823(g)(2)(B)(iii). And if a patient was lucky enough to find a provider who was accepting new patients, that treatment was often not covered by patient's insurance and was unaffordable to pay out of pocket. Because of the abundance of MAT providers in Pennsylvania, however, it was much easier for patients to get into a treatment program there. Plus, the Pennsylvania providers were more affordable and required fewer in-office visits, which meant that MAT patients could maintain their job and go to their MAT provider once or twice a month. By contrast, it was not uncommon for providers in West Virginia to require appointments weekly, or more often, which made it nearly impossible to hold a job while getting treatment. In short, Pennsylvania providers were more available, more affordable, and more workable. Going to those providers was not a red flag, it was instead a helpful step toward treatment and recovery from opioid dependence.

Likewise, the OHHP staff explained that the distance travelled by patients to OHHP was a product of West Virginia and its communities. For one, much of West Virginia and the area surrounding Oak Hill is rural and a lot of people in that area live a long way from businesses like pharmacies. Just to get to a convenience store can require miles and miles of driving on mountainous, curvy roads. Even if patients lived in communities with a pharmacy, many pharmacies in the State refused to fill Subutex because of the stigma associated with it and those who take it — that is, patients suffering from addiction and opioid use disorder. Assuming, however, that a patient was able to find a pharmacy close to them that did fill Subutex, some patients chose not to frequent those pharmacies for fear that news of their treatment status would spread throughout their small communities.

Turning to the second supposed red flag — the medication itself, Subutex — the OHHP staff dispelled that concern as well. The DEA agents expressed concern that Subutex and not Suboxone was being prescribed and filled. According to the DEA, Suboxone was a more appropriate medication for MAT and in most cases, Subutex had no legitimate medical use. But Subutex is and was an FDA-approved medication for use in MAT, the exact treatment for which the patients at OHHP were filling their Subutex prescriptions. Moreover, Subutex was more affordable than Suboxone. Because health insurance would not cover these patients' MAT prescriptions, cost was a legitimate concern of patients who were trying to get help for their opioid use disorder. That legitimate cost concern also explained why patients often only purchased partial fills of their Subutex prescriptions. Patients would receive partial fills at regular intervals as they could afford to, instead of getting their full Subutex prescriptions at one time. With insurance refusing to cover those prescriptions, most patients could simply not afford to fill their entire prescription at once.

After the DEA served the administrative warrant, OHHP sought to reduce its filling of Subutex prescriptions. Although OHHP and its staff did not believe that it had left any potential red flags unresolved, Dr. Njoku and OHHP made the decision to exercise excess caution. OHHP still wished, however, to help combat the opioid epidemic. So, OHHP decided to only fill Subutex prescriptions for a select group of roughly 20 patients after that November 2018 administrative warrant. And by January of 2019, OHHP had further reduced that to just seven patients — multiple pregnant woman, people who could not take Suboxone because of an allergy or adverse health impacts, and a single cancer patient who received the medication for pain, not addiction.

C. OHHP fills new Subutex prescriptions for small select group of patients in need and DEA immediately suspended OHHP's registration without notice or an opportunity to respond.

OHHP continued to fill Subutex prescriptions for that select group of seven patients until August 8, 2019, when DEA agents again entered OHHP. From January 1, 2019 until the DEA arrived at OHHP again, OHHP had filled a total of 68 Subutex prescriptions for that group of patients. *See* Exhibit 3, at ¶ 21. But this time when they entered, those agents did not merely serve an administrative warrant and interview OHHP's employees. Instead, they served the Ex Parte Suspension Order, seized OHHP's Registration, confiscated its controlled substances, and effectively shut down OHHP's pharmacy business.

The Ex Parte Suspension Order generally alleged that OHHP continued improperly dispensing Subutex *after* the November inspection. That allegation was based on the same supposed red flags that the DEA agents had discussed with the OHHP staff back in November: the prescriptions were for Subutex and not Suboxone; those prescriptions were written by out of state providers, whose patients had travelled a sizeable distance to visit them and who were treating multiple West Virginia patients on the same day; the prescriptions were paid privately and without insurance (or, as the Government likes to call it, "paid for in cash," even though those "cash" payments include those made with cash, checks, debt cards, and credit cards); the patients travelled to fill their prescriptions at OHHP; and that OHHP filled, over a multi-year period, an average of seven of those prescriptions a day. According to the Ex Parte Suspension Order — despite the reasonable and real-life explanations provided by the OHHP staff for each of those concerns — those were red flags that "were highly indicative of abuse and diversion." *See* Exhibit 2, at 8.

The Ex Parte Suspension Order also identified that OHHP had continued to fill Subutex prescriptions "through at least March 2019," which the Government referred to as "ongoing

conduct." *See* Exhibit 2, at 8. That order repeated all of the same red flags that were supposedly raised by filling those Subutex prescriptions. The Ex Parte Suspension Order asserted that the Government's expert had reviewed 43 Subutex prescriptions that OHHP had filled from December 2018 to March 2019 — that is, an average of about 10 Subutex prescriptions *a month* — and that those prescriptions presented the same red flags as before. Finally, the Ex Parte Suspension Order contended that there is "no legitimate need for Subutex." *See id.* at 10.

Based on those allegations, the Administrator who issued the Ex Parte Suspension Order reached two preliminary findings. The first preliminary finding — the Show Cause Finding — was that OHHP's Registration is "inconsistent with the public interest" because it filled Subutex prescriptions without resolving what were supposedly red flags of diversion. That preliminary finding went to the standard provided in 21 U.S.C. § 824(c). Section 824(c) requires that before revoking a pharmacy's registration, the DEA must serve upon it "an order to show cause as to why registration should not be . . . revoked." *See* 21 U.S.C. § 824(c). That section does not permit, however, for the revocation or suspension of a registration before that pharmacy has had the opportunity to respond to the allegations either by "a corrective action plan" or an administrative proceeding. *See id.* In other words, the typical procedure for revoking or suspending a registration requires notice and an opportunity to be heard.

But by way of his second preliminary finding — the Immediate Suspension Finding — the Administrator sought to immediately suspend OHHP's Registration without permitting it the opportunity to respond. That preliminary finding read as follows:

> significantly in light of the rampant and deadly problem of prescription controlled substance abuse, that OHHP's continued registration during the pendency of these proceedings would constitute "an imminent danger to the public health or safety" because of the substantial likelihood that OHHP will continue to unlawfully *prescribe* controlled substances, thereby

> allowing the diversion of controlled substances, unless OHHP's [Registration] is suspended.

See Exhibit 2, at 12 (emphasis added). The Administrator, based on that preliminary finding, immediately suspended OHHP's Registration pursuant to 21 U.S.C. § 824(d). Section 824(d) permits the DEA Administrator to suspend, *ex parte*, any registration where "he finds that there is an imminent danger to the public health or safety." *See* 21 U.S.C. § 824(d); *see also* 21 C.F.R. § 1301.36(e). Importantly, the statute provides a definition of "imminent danger to the public health or safety," which means that

> due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations . . . there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in absence of an immediate suspension of the registration."

See id. at §824(d)(2). In order to immediately suspend a registration under that provision, the Administrator must provide "a statement of his findings regarding the danger to public health or safety." *See* 21 C.F.R. § 1301.36(e). And a suspension under that section continues until "withdrawn by the Attorney General or dissolved by a court of competent jurisdiction." *See id.*[3] In essence, an immediate suspension — without notice or an opportunity to be heard — is appropriate in the extraordinary, not merely ordinary situation.

Consistent with the immediate suspension of OHHP's Registration, the DEA agents confiscated all of OHHP's controlled medications and effectively halted its ability to serve as complete pharmacy for its patients. OHHP was not permitted an opportunity to respond to those allegations prior to DEA's actions. OHHP was not permitted an opportunity to explain that OHHP had diligently detected and resolved potential warning signs of diversion or that the DEA was

[3] Pursuant to regulations, the Attorney General has delegated his duties to the Administrator of the DEA. *See* 28 C.F.R. § 0.100.

mistaken about what it believed were the red flags. OHHP was not permitted an opportunity defend against the incorrect beliefs and assertions of the DEA.

D. OHHP business is crippled, it is forced to lay off employees, and it is faces impending closure.

Left without a certificate of registration to fill any prescriptions for controlled medications, OHHP quickly began to lose patients. Other patients were scared away by the press and media blitz conducted by the Government against OHHP. The Government issued a press release that contained salacious-sounding allegations about OHHP's filing of Subutex; the United States Attorney for the Southern District of West Virginia contemporaneously tweeted about the action against OHHP from his official and personal twitter accounts.

Unable to respond to those attacks, and despite only trying to aid in the MAT of patients who were seeking help with their opioid use disorder, OHHP's business started to shrivel. It quickly had to lay off employees, received threats from its distributors that it would be cut off from further medication orders, and had to take out a line of credit just to keep the lights on. *See* Exhibit 3, at ¶ 22. Given this state of affairs and the financial pressures — as attested to by OHHP's part owner, Dr. Njoku — OHHP will likely close in the very near future, without some resolution or reinstatement of its Registration. *See id.*

II. ARGUMENT

The Administrator's basis for his *ex parte*, immediate suspension of OHHP's Registration is woefully insufficient. Not only did the Administrator effectively shut down OHHP's business based upon mistaken views of real-life circumstances in West Virginia, but he also simply got some of those facts *wrong*.

Because OHHP, as demonstrated below, meets the requirements for preliminary injunctive relief, this Court should dissolve the immediate suspension and reinstate and restore OHHP's

Registration. In order obtain a preliminary injunction, a plaintiff must demonstrate four elements: (A) that it is "likely to succeed on the merits;" (B) that it "will likely suffer irreparable harm absent an injunction;" (C) that "the balance of hardships weigh in [its] favor;" and (D) that "the injunction is in the public interest." *See League of Women Voters of N.C. v. N.C.*, 769 F.3d 224, 236 (4th Cir. 2014). Faced with an erroneous and wrongful immediate suspension of its Registration, OHHP faces near certain closure, and the community of Oak Hill would be deprived of one of the few pharmacies willing to fill necessary prescriptions to help opioid dependent West Virginians.

A. OHHP is likely to succeed on the merits because the Administrator's immediate suspension is fatally erroneous in multiple respects.

The Administrator's immediate *ex parte* suspension suffers from three insurmountable errors: (1) the preliminary finding was factually incorrect, (2) the stated bases of the suspension were insufficient, and (3) the suspension was not sufficiently tailored based on the Administrator's allegations. Those separate and independently sufficient errors demonstrate that OHHP will likely succeed on demonstrating that the Administrator has not met the standard for immediate suspension in 21 U.S.C. § 824(d).

1. The Administrator's Preliminary Immediate Suspension Finding is factually incorrect and totally unsupportable.

The Administrator's Preliminary Immediate Suspension Finding relates facts that are not, and cannot be, correct. By doing so, the Administrator failed to demonstrate that there "is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in absence of an immediate suspension of the registration." *See* 21 U.S.C. § 824(d)(2). Thus, the Administrator's Preliminary Immediate Suspension Finding fails to meet the statutory standard for an immediate *ex parte* suspension of a registration, and the immediate suspension of OHHP's Registration must be dissolved.

In declaring its preliminary finding for the immediate suspension, the Administrator relied upon a totally unsupported falsity. The immediate suspension rests entirely upon the preliminary finding that there was "the substantial likelihood that OHHP will continue to unlawfully *prescribe* controlled substances, thereby allowing the diversion of controlled substances." *See* Exhibit 2, at 12 (emphasis added). But OHHP has *never prescribed* a medication. *See* Exhibit 3, at ¶ 5. OHHP is a pharmacy that *fills* prescriptions. *See id.* Doctors or licensed practitioners are the only people who can *prescribe* medication. *See* 21 U.S.C. § 802(56) (explaining that pharmacies fill or dispense prescriptions for controlled substances and practitioners issue prescriptions). Due to that fundamental falsity — that is, the entire rationale that supported the immediate suspension — the Preliminary Immediate Suspension Finding is grossly insufficient. Based upon that basic error alone, the immediate suspension should be dissolved and OHHP's Registration reinstated.

2. The stated bases of the Ex Parte Suspension Order fail to satisfy the statutory standard for an immediate *ex parte* suspension of OHHP's Registration.

In addition to the insufficiency of the Administrator's Preliminary Immediate Suspension Finding, the supposed red flags that undergird the immediate suspension of OHHP's Registration fail to support that suspension. The red flags alleged by the Administrator fall into three buckets: (1) distance; (2) medication; (3) and private payment of partial prescription fills. But those allegations of supposed red flags of diversion do not acknowledge the on-the-ground circumstances that exist in West Virginia, which force patients to travel extended distances, receive Subutex prescriptions, and pay for those prescriptions privately and in the smaller increments of partial fills.

Those supposed red flags are not, in actuality, "highly indicative of abuse and diversion." *See* Exhibit 2, at 10. Instead, those circumstances are a product of a lack of MAT providers and

pharmacies who would fill MAT prescriptions. Thus, patients seeking help with their opioid dependence were forced to travel to Pennsylvania to receive treatment. And when those patients returned with duly written prescriptions, they were often turned down by local pharmacies that would not fill Subutex due to the stigma of treating patients who suffer from addiction. *See* Exhibit 3, at ¶ 12. Sometimes, even if a local pharmacy would fill such a prescription, the patients steered clear, fearing that they would become the object of stigma or ridicule in their small communities due to their MAT prescription. Moreover, Subutex is an appropriate MAT prescription that is FDA-approved for treatment of opioid use disorder and is also more affordable than Suboxone. *See* Exhibit 3, at ¶¶ 3-4. Although more affordable, patients were still forced to pay privately for those prescriptions because of a lack of insurance coverage and often had to purchase partial fills of their prescriptions due to the inability to afford the whole prescription at one time. *See* Exhibit 3, at ¶ 19. Those circumstances are not indicative of abuse or diversion, but are instead indicative of perseverance and hardship.

Based on his misapprehension of, and disregard for, the factual circumstances surrounding MAT therapy, the Administrator failed to provide a sufficient basis for a "substantial likelihood" determination. *See Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency findings are insufficient where they fail to consider an important aspect of an issue). The "substantial likelihood" standard, as implemented in federal statutes, is a "more stringent" standard. *See Radol v. Thomas*, 772 F.2d 244, 253 (6th Cir. 1985) (differentiating substantial likelihood standard within the context of federal securities statutory structure). That standard is not satisfied by a mere possibility or conceivability that something was likely to occur. *See id.* Where each of the potential indications of abuse or diversion not only has an explanatory justification, but is also a creation of a totally inadequate system for treating

the many West Virginians who struggle with opioid use disorder, the Administrator has failed to meet the more stringent standard of substantial likelihood. *See Bates Drug Stores, Inc. v. Holder*, No. CV-11-0167-EFS, 2011 WL 1750066, at *3 (E.D. Wash. May 6, 2011) (recognizing in context of temporary restraining order application that that DEA is unlikely to establish "imminent danger to public health or safety" without evidence that a controlled substance was dispensed to improper individual, for an improper purpose, or in an improper dosage); *see also Holiday CVS, L.L.C. v. Holder*, 839 F.Supp.2d 145, 163 (D.D.C. 2012), *vacated on other grounds by*, 493 Fed. App'x 108 (D.C. Cir. Nov. 26, 2012) (denying preliminary injunction of immediate suspension where "the pharmacists [had] admitted" to failing "to detect warning signs [of abuse]"). Thus, the Administrator has not satisfied the showing for issuing an immediate *ex parte* suspension of OHHP's Registration. That suspension should be dissolved, and OHHP's Registration should be reinstated pending the final order of the separate administrative proceedings regarding the Show Cause Finding pursuant to § 824(c).

3. Even if its Preliminary Immediate Suspension Finding was adequately supported, the immediate suspension of OHHP's Registration was overly broad and insufficiently tailored.

Although the Ex Parte Suspension Order addresses only allegations concerning OHHP's filling of prescriptions for a single medication, Subutex, the Administrator suspended OHHP's Registration in its entirety. The Administrator thus prohibited OHHP from filling prescriptions for *any* controlled medication, not just Subutex. That suspension, however, is overly broad and not sufficiently tailored to the actions that allegedly caused imminent harm to the public health or safety — filling prescriptions for Subutex. The Ex Parte Suspension Order does not allege that OHHP filled any other medications incorrectly, not Suboxone, not Xanax, nor any other controlled medication. Despite the ability to do so, the Administrator did not limit its suspension just to the

medication at issue — Subutex — and thereby exceeded the bases provided in the Ex Parte Suspension Order.

The Government's immediate suspension of OHHP's ability to fill controlled substances is not supported by its allegations. Generally, courts do not permit the DEA's "choice of sanction" to stand if that "sanction is either unwarranted in law or . . . without justification in fact." *See Morall v. DEA*, 412 F.3d 165, 181 (D.C. Cir. 2005) (internal quotation marks omitted) (parenthetically quoting *Bluestone Energy Design, Inc. v. FERC*, 74 F.3d 1288, 1294 (D.C. Cir. 1996)). Indeed, such injunctive actions must be "closely tailor[ed] . . . to the harm that they address." *See ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 972 (D.C. Cir. 1990) (discussing district court injunction). And, as provided by statute, the Administrator has the ability to "limit revocation or suspension of a registration to the particular controlled substance . . . with respect to which grounds for revocation or suspension exist." *See* 21 U.S.C. § 824(b). But the Administrator refused to so limit the suspension here. Similarly important, the Administrator also failed to explain why a less restrictive suspension would not be appropriate given the limited nature of his allegations.

By prohibiting OHHP from filling any prescriptions for controlled substances, the Administrator has crippled OHHP's ability to dispense medications to its patients. The Administrator's immediate suspension must, at the very least, be limited only to Subutex. *See United States v. Gelb*, 826 F.2d 1175, 1177 (2nd Cir. 1987) (recognizing that it may be necessary to limit "ex parte orders" to "avoid unnecessary or collateral effects"). Such a suspension would be the only suspension that the Administrator's allegations could possibly support — even though OHHP continues to maintain that those allegations are incorrect and insufficient for any immediate *ex parte* suspension.

B. OHHP will suffer irreparable harm absent an injunction because it will be forced to shut down as a business.

Without injunctive relief by this Court, OHHP will most certainly close in the near future, and thus the second prong for preliminary injunctive relief is satisfied. OHHP has already had to lay off most of its employees. *See* Exhibit 3, at ¶ 22. OHHP has also had to take on debt just to keep the lights on, for now. *See id.* And without the ability to fill controlled medications, OHHP will continue to lose patients and will have to shut its doors. *See id.* Moreover, monetary damages will not be able to compensate OHHP for having to close its doors for good. In other words, OHHP meets the irreparable harm prong. *See NaturaLawn of Am., Inc. v. West Group, LLC*, 484 F.Supp.2d 392, 401 (D. Md. 2007) (finding irreparable harm where plaintiff's operations would be effectively shut down).

C. The balance of hardships weighs in favor of granting the injunction.

Likewise, the third prong for a preliminary injunction — the balance of hardships — is met. Whereas OHHP will almost certainly go out of business, the DEA does not face a similarly severe hardship. Indeed, the administrative proceedings to determine whether OHHP's Registration should be revoked will continue and will not be hindered by this Court's action. In those proceedings, the DEA will have the opportunity to demonstrate that OHHP's Registration is inconsistent with the public interest. And OHHP will have a similar opportunity to rebut that effort. In essence, the DEA does not face a hardship if this Court enjoins and dissolves the immediate suspension. The balance of hardships weighs heavily in favor of dissolving the immediate suspension.

D. The injunction is in the public interest because OHHP serves a vital and important role in the Oak Hill community.

Finally, the fourth prong is similarly fulfilled; the public interest weighs in favor this Court granting OHHP's request for a preliminary injunction to dissolve the immediate suspension. Like many small West Virginia communities, Oak Hill lacks an abundance of pharmacies. *See* Exhibit 3, at ¶ 1. Indeed, OHHP serves a critical role in the community by providing a local pharmacy where members of that small community can fill their needed prescriptions. Without OHHP, patients in Oak Hill and the surrounding area would be deprived of an important link in the chain of their medical treatment. Therefore, the public interest favors granting the injunction.

III. CONCLUSION

The Administrator failed to meet the statutory standard for immediately suspending OHHP's Registration. The Administrator relied on insufficient bases and reached a plainly false preliminary finding. But even if its immediate suspension was cured of those fundamental errors, the extent and breadth of the immediate suspension of OHHP's Registration would still be unsupported. Because OHHP satisfies the four prongs for preliminary injunctive relief, this Court should correct the Administrator's mistake and dissolve the *ex parte* suspension order.

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Respectfully submitted,
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